CDER Export Certificate Program Frequently Asked Questions (FAQs)

Q. What is an FDA CDER issued Export Certificate?

A. An FDA CDER issued Export Certificate is a Certificate of Pharmaceutical Product (CPP). It is a document prepared by FDA that contains information about the product's regulatory or marketing status and it follows the World Health Organization (WHO) scheme.

Q. Do I need a CPP to export drugs regulated by CDER?

A. No. But it is the exporter's responsibility to determine the requirements and laws of the importing country.

Q. Do I have to be a manufacturer to request a CPP?

A. No. Anyone who can submit a complete CPP application can request a CPP for a specific drug and desired country.

Q. How long does it take to get a CPP application processed?

A. FDA normally issues certificates within twenty (20) government working days of receipt of an accurate and complete CPP application. In some cases if the application is not correct or if inaccurate information is submitted, then issuance of a certificate can be denied or issuance of a certificate can be longer than twenty (20) days.

Q. What is the cost of a CPP?

A. When the FDA issues a certificate within 20 days of receipt we can charge a maximum of $175 per certificates. Currently the fees are:

First Certificate (original):	$175.00
Second Certificate (same drug & country):	$90.00
Third & subsequent certificates (same drug & country):	$40.00

Q. Is there a limit to the number of certificates that I can request at the same time?

A. No. There are no restrictions on the number of certificates that can be requested per CPP application.

Q. How many copies of the labeling and attachments do I need to provide with my CPP application?

A. A copy of the labeling is required for each country per application, plus one copy for FDA's record.

Q. May I submit one CPP application for multiple drugs?

A. No. You may submit one (1) drug per CPP application.

Q. May I submit one CPP application for multiple countries?

A. Yes. You may submit one (1) application for each drug indicating the countries desired.

Q. **Can products with the same NDA number and the same dosage form, but with different potencies be processed on the same certificate?**

A. Yes. One approved drug application may include multiple potencies. FDA can issue an export certificate for all potencies under one approval.

Q. Does FDA issue CPPs for excipients?

A. No. CPPs are not issued for excipients.

Q. What color ribbon will be attached to the CPP?

A. Red Ribbon – approved drug product; Active Pharmaceutical Ingredient (API); OTC marketed per monograph; & export only drugs.

Blue Ribbon - unapproved drug product not marketed in the U.S.

Yellow Ribbon – drug manufactured outside of the U.S.

Q. Can I apply for a CPP for an FDA approved drug manufactured and exported from a country other than the United States?

A. Yes. You may submit an application to obtain a "Pilot" CPP. FDA may issue CPPs for drugs that are FDA-approved, but are manufactured or finished in, and exported from, a country other than the United States.

Q. How long is a CPP valid?

A. A CPP expires twenty four (24) months from the date authorized.

Q. Who should I contact if I have certificate questions?

A. You may submit export certificate questions by email to the exports certificate mailbox at: CDERExportCertificateProgram@FDA.hhs.gov or you may call the Export Certificate Telephone number, 301.796.4950 and leave a message.

Q. Where do I mail my applications?

A. Food and Drug Administraion
Center for Drug Evaulation and Research
Export Certificate Program
10903 New Hampshire Avenue
Building 51, Room 4249
Silver Spring, MD 20993-0002

Q. Where can I obtain copies of the export certificate application? (form 3613b)

A. You may download the form at:
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM052388.pdf